

Remarks

The claims have been amended in herein to overcome the rejections made in the Office Action. Applicants do not concede, by these claim amendments, that the Office Action's rejections are correct or accurate. However, in an effort to expedite allowance of this application, amendments have been made to the claims to put the case in a favorable condition for allowance.

Applicants respond herein in the order issues were presented in the Office Action.

1. Rejection under § 112 ¶ 1; Enablement

Applicants note the rejection made in the Office Action under § 112 ¶ 1 relating to enablement. Claims have been amended with respect to this rejection to include only those peptides with a C-terminal KPV that have an amino acid length of between 3 and 13 amino acids. Support may be found in the specification for this amendment in the Brief Description of Figures, showing peptides of 3 and 13 amino acids with a C-terminal KPV; at ¶ [0021], *inter alia*, of the Summary of the Invention, showing peptides between 3 and 13 amino acids in length with a C-terminal KPV; ¶¶ [0065-68], *inter alia*, of the Detailed Description, showing peptides between 3 and 13 amino acids in length with a C-terminal KPV; and, in original claim 2, *inter alia*, showing peptides between 3 and 13 amino acids in length with a C-terminal KPV. An artisan, given the amended claims and the specification as written, would be able to determine which peptides within this genus, being much smaller, would be effective.

The limitation of the claims to peptides of 3-13 amino acids in length so limits the breadth of the claims that the guidance provided by the specification, as regards enablement, is adequate. The amended claims are directed to a much smaller genus

that include only those peptide sequences of 3-13 amino acids in length having a C-terminal KPV. Thus, there is more predictability in the invention claimed. The specification, by focusing on the anti-microbial and anti-inflammatory aspects of the genus, gives adequate guidance of this.

As noted above, the specification includes support for at least four separate sequences of between 3-13 amino acids in length having a C-terminal KPV. Further, support exists in the Examples for an amendment to the claims in which the amino acid length is between 3-13. Example 1, for example, shows 3, 8 and 13 amino acid peptides bearing a C-terminal KPV. The same is true of Example 2. Both examples show working species of α -MSH (1-13), (6-13) and (11-13) which fall within the genus of 3-13 amino acid peptides having a C-terminal KPV. Example 10 further shows a working species involving the KPV dimer, referred to in the specification, at ¶ [0134], as (CKPV)₂.

The specification, then, shows that a number of species of the claimed invention are effective. No experimentation outside that which would be considered reasonable by one of ordinary skill in the art is necessary to practice the invention. Moreover, it is noted in the Office Action, the specification is "enabling for a pharmaceutical composition using alpha-MSH ending in SEQ ID NO: 1." (Office Action at 2-3). In addition, the specification gives working examples, and suggests well-known methods to create the peptides of the invention; for example, attention is directed to page 16 of the specification.

It is respectfully requested that favorable consideration be given the claims as amended, and that the § 112 ¶1 rejection be removed.

2. Rejection under § 112 ¶2; Written Description

Given the limitation of the number of amino acids, there are more common structural attributes of the members of the genus. One ordinarily skilled in the art would appreciate the efficacy of peptides of 3-13 amino acids in length, given the instant written description, as peptides of those lengths have been shown to be effective in the Examples disclosed. An artisan would respect that the inventors herein had possession of the claimed invention, as there is adequate support in the specification to support the claims as amended.

According to the Office Action:

In order to fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus." (Office Action at 5).

Here, the written description provides numerous common structural attributes of the genus. First, in the claims as amended, the genus includes those peptides of between 3 and 13 amino acids in length in which the peptide contains a C-terminal KPV. More than identifying a single species of the claimed genus, the written description fully describes four species of this genus, including examples, as noted above. Examples of KPV (SEQ ID NO: 1), (CKPV)₂ (SEQ ID NO: 4), α -MSH (6-13) (SEQ ID NO: 2) and α -MSH (1-13) (SEQ ID NO: 3) are fully described and tested in the examples and specification.

It is also noted in the Office Action that an artisan need be able to "identify the common characteristics of the claimed molecules." (Id). The amended claims significantly reduce the number of peptides within the genus and curtails the number of structural variants. The claimed genus distinguishes itself from other compounds in the protein class by nature of its length and structure.

First, the artisan knows that the molecule claimed comprises between 3-13 amino acids. Second, the artisan knows that the C-terminal aspect of the 3-13 amino acid molecule is pre-determined to be KPV. Moreover, the artisan knows from the written description that the molecule is anti-microbial and anti-inflammatory.

Applicants respectfully request the § 112 ¶2 rejection be withdrawn.

Conclusion

In light of the above, Applicant's request favorable consideration of the claims as amended. Any questions may directed to the undersigned.

Dated: 6/21/04, 2004

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